K093550

JAN - 7 2010

6. 510(k) Premarket Notification
Summary of Safety and Effectiveness

Submission Information

Manufacturer: Small Bone Innovations, Inc.
1380 South Pennsylvania Avenue
Morrisville, PA 19067
Ph: 215-428-1791 Fax: 215-428-1795

Submitted By: Small Bone Innovations, Inc.
John Minier
1380 South Pennsylvania Avenue
Morrisville, PA 19067

Proprietary Name: SBi Mini Rail External Fixation System

Classification name: Class II, 21 CFR 888.3030 – Single/multiple component metallic bone fixation appliances and accessories

Product Code: KTT

Common/Usual Name and Reference Number:
appliance, fixation, nail/blade/plate combination, multiple component, 21 CFR 888.3030

Substantial Equivalence: Documentation is provided which demonstrated the SBi Mini Rail External Fixation System to be substantially equivalent to other legally marketed devices.

Device Description: The SBi Mini Rail External Fixation System consists of pins of various diameters and lengths as well as the rails and accessories with which to connect and stabilize them. The system also includes instruments to implant the pins and connect the external components. A tray is included to store and transport the set. The devices are supplied non-sterile.

Intended Use: The SBi Mini Rail External Fixation System is intended for fixation, compression, and distraction osteo-genesis of small bones, such as metacarpal and metatarsal. The system also includes the instruments with which to place the pins and assemble the construct. A tray is available for conveying and storing the system. The system is not intended for spinal use.

The pins and external connecting components are intended for single use only.
The implants are intended for single use only.

Materials: The pins are made from implant grade 316LS stainless steel (ASTM F138). The external components are made from medical grade aluminum and stainless steel.

Predicate Devices: The modified device is equivalent to the cleared SBi (formerly Fixano) MiniFIX External Fixator K964094.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JAN - 7 2010

Small Bone Innovations, Inc.
% Mr. John Minier
Regulatory Affairs Director
1380 South Pennsylvania Avenue
Morrisville, Pennsylvania 19067

Re: K093550
Trade/Device Name: SBi Mini Rail External Fixator System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories.
Regulatory Class: Class II
Product Code: KTT
Dated: December 10, 2009
Received: December 11, 2009

Dear Mr. Minier:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

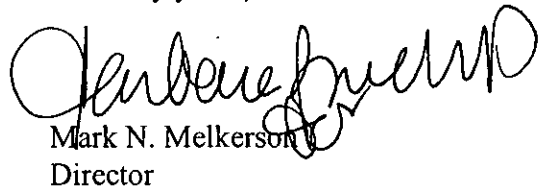
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K093550

5. Statement of Indications for Use

510(k) Number:

Device Name: SBi Mini Rail External Fixation System

Indications For Use:

The SBi Mini Rail External Fixation System is indicated for use in external fixation of fractures and/or reconstruction of small bones, including metacarpal and metatarsal.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093550